

**INTEGRITY AGREEMENT  
BETWEEN THE  
OFFICE OF INSPECTOR GENERAL  
OF THE  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
AND  
LEONARD GINSBURG, M.D.**

**I. PREAMBLE**

Leonard Ginsburg, M.D. hereby enters into this Integrity Agreement (Agreement) with the Office of Inspector General (OIG) of the United States Department of Health and Human Services (HHS) to promote compliance with the statutes, regulations, program requirements, and written directives of Medicare, Medicaid, and all other Federal health care programs (as defined in 42 U.S.C. § 1320a-7b(f)) (“Federal health care program requirements”). This commitment to promote compliance applies to any entity that Leonard Ginsburg owns or in which he has a control interest (Ginsburg entity), as defined in 42 U.S.C. § 1320a-3(a)(3), and Leonard Ginsburg’s and any such entity’s Covered Persons as defined in Section II.C. For purposes of this Agreement, Leonard Ginsburg and the Ginsburg entities are collectively referred to as “Ginsburg.” Contemporaneously with this Agreement, without admitting fault or liability, Ginsburg is entering into a Settlement Agreement with the OIG, and this Agreement is incorporated by reference into the Settlement Agreement.

**II. TERM OF THE AGREEMENT**

A. The date on which the final signatory of this Agreement executes this Agreement shall be known as the Effective Date. The period of compliance obligations assumed by Ginsburg under this Agreement shall be three years from the Effective Date of this Agreement. Each one-year period beginning with the one-year period following the Effective Date, shall be referred to as a “Reporting Period.”

B. Sections VII, VIII, IX, X, and XI shall expire no later than 120 days from OIG’s receipt of: (1) Ginsburg’s final Annual Report; or (2) any additional materials submitted by Ginsburg pursuant to OIG’s request, whichever is later.

C. The scope of this Agreement shall be governed by the following definitions:

1. “Covered Persons” includes:

- a. all owners, officers, directors, associates, and employees;
- b. all contractors, agents, and other persons who provide patient care items or services or who perform billing or coding functions on behalf of Ginsburg; and
- c. all other individuals responsible for the provision, marketing, or documentation of items or services reimbursable by Federal health care programs, or in the preparation of claims, reports, or other requests for reimbursement for such items or services on behalf of Ginsburg.

### **III. INTEGRITY OBLIGATIONS**

Ginsburg has previously established and will maintain a Compliance Program that includes the following elements:

#### **A. Compliance Contact**

Within 30 days after the Effective Date, Ginsburg shall designate a person or persons to be responsible for compliance activities (“Compliance Contacts”). The Compliance Contacts shall be responsible for: (1) developing and implementing policies, procedures, and practices designed to ensure compliance with the requirements set forth in this Agreement and with Federal health care program requirements; (2) monitoring Ginsburg’s day-to-day compliance activities; and (3) meeting all reporting obligations created under this Agreement.

Ginsburg shall report to OIG, in writing, any changes in the identity or job responsibilities of the Compliance Contact, or any actions or changes that would affect the Compliance Contact’s ability to perform the duties necessary to meet the obligations in this Agreement, within 15 days after such change. The name, address, phone number, and a description of any other job responsibilities performed by the Compliance Contact shall be included in the Implementation Report.

#### **B. Posting of Notice**

Within the 90 days after the Effective Date, Ginsburg shall post in a prominent place accessible to all patients and Covered Persons notices detailing his commitment to comply with all Federal health care program requirements in the conduct of his business.

These notices shall also include the following information: (i) a means (e.g., telephone number or address) by which instances of misconduct may be reported anonymously; and (ii) Ginsburg's commitment to maintain the confidentiality of the report. With respect to the notification to Covered Persons only, the notice shall further state that reporting a suspected violation will not result in retribution or retaliation by Ginsburg. A copy of this notice shall be included in the Implementation Report.

**C. Written Policies and Procedures**

Within 90 days after the Effective Date, Ginsburg shall develop, implement, and distribute written Policies and Procedures to all Covered Persons. In addition, Ginsburg shall make the promotion of, and adherence to, the written Policies and Procedures an element in evaluating the performance of all employees. The written Policies and Procedures shall, at a minimum, set forth:

1. Ginsburg's commitment to full compliance with all Federal health care program requirements, including the commitment to prepare and submit accurate claims consistent with such requirements and including the requirements with respect to the provision and documentation of medically necessary health care items or services;
2. the expectation that all of Ginsburg's Covered Persons shall be expected to comply with all Federal health care program requirements and with Ginsburg's own written Policies and Procedures as implemented pursuant to this Section III.C (including the requirements of this Agreement);
3. the responsibility and requirement that all Covered Persons report suspected violations of any Federal health care program requirements or of Ginsburg's own Policies and Procedures to the Compliance Contact and Ginsburg's commitment to maintain confidentiality and anonymity, as appropriate, and not to retaliate with respect to any patient or Covered Person with respect to any such disclosures;
4. the possible consequences to both Ginsburg and Covered Persons of failure to comply with Federal health care program requirements or with Ginsburg's written Policies and Procedures and the failure to report such noncompliance;

5. Ginsburg's commitment to remain current with all Federal health care program requirements by obtaining and reviewing program memoranda, newsletters, and any other correspondence from the carrier related to Federal health care program requirements;
6. the proper procedures for the accurate preparation and submission of claims in accordance with Federal health care program requirements;
7. the proper documentation of services and billing information;
8. policies and procedures designed to promote and monitor compliance with 42 U.S.C. § 1320a-7b(b) (the "Anti-Kickback Statute") and 42 U.S.C. § 1395nn (the "Stark Law"), and the regulations and other guidance documents related to these statutes, and business or financial arrangements or contracts that induce the unlawful referral of Federal health care program beneficiaries in violation of the Anti-Kickback Statute or the Stark Law;
9. The requirements set forth in Section III.D;
10. policies and procedures for performing semi-annual internal audits and reviews that would make finding regarding whether patients are receiving health care items and services that are medically necessary in accordance with professionally recognized standards of care for the geographic area in which Ginsburg resides; and
11. policies and procedures for coordination and compliance with utilization review protocols (e.g., clinical indications) in conjunction with any hospital, or committee thereof, with which Ginsburg has admitting privileges to ensure that Ginsburg's or any Covered Person's arranging, ordering, or provision of any hospital based health care item or service, for any individual, whether or not a Federal health care program patient or recipient, does not violate the statutory obligations for health care practitioners at 42 U.S.C. § 1320c-5(a).

Within 30 days after the implementation of the Policies and Procedures, each Covered Person shall certify in writing that he or she has received, read, understood, and shall abide by Ginsburg's written Policies and Procedures. New Covered Persons shall receive and review the written

Policies and Procedures and shall complete the required certification within 30 days after becoming a Covered Person or within 30 days after the implementation of the Policies and Procedures, whichever is later.

At least annually (and more frequently if appropriate), Ginsburg shall assess and update, as necessary, the Policies and Procedures. Within 30 days after the effective date of any revisions, the relevant portions of any such revised Policies and Procedures shall be distributed to all Covered Persons. Appropriate and knowledgeable staff shall be available to explain the Policies and Procedures.

Copies of the written Policies and Procedures shall be included in the Implementation Report. Copies of any written Policies and Procedures that are subsequently revised shall be included in the next Annual Report along with a summary of any change or amendment to each Policy and Procedure required by this Section and the reason for each change.

**D. Training and Certification**

Within 120 days after the Effective Date and at least once each year thereafter, Leonard Ginsburg and Covered Persons, to the extent relevant to their functions, shall receive at least three hours of training from an individual or entity, other than Leonard Ginsburg or another Covered Person. Persons providing the training shall be knowledgeable about the subject area and may be received from a variety of sources (e.g., CME classes, hospitals, associations, carriers).

New Covered Persons shall receive the training described above within 30 days after becoming a Covered Person or within 120 days after the Effective Date, whichever is later. The training for new Covered Persons may either be provided internally by a Covered Person who has completed the required annual training or externally by a qualified individual or entity. A new Covered Person shall work under the direct supervision of a Covered Person who has received such training, to the extent that the work relates to the delivery of patient care items or services and/or the preparation or submission of claims for reimbursement from any Federal health care program, until such time as the new Covered Person completes the training.

At a minimum, the initial, annual, and new employee training sessions shall include the following topics:

1. the requirements of this Agreement;

2. an overview of the Ginsburg's compliance program;
3. the accurate coding and submission of claims for services rendered and/or items provided to Federal health care program beneficiaries;
4. applicable reimbursement statutes, regulations, and program requirements and directives;
5. the written Policies and Procedures developed pursuant to Section III.C, above;
6. the policies, procedures, and other requirements applicable to the documentation of medical records;
7. the personal obligation of each individual involved in the coding and claims submission process to ensure that such claims are accurate;
8. the legal sanctions for the submission of improper claims or violations of the Federal health care program requirements;
9. examples of proper and improper coding and claim submission practices;
10. the legal sanctions for improper contracting or entering into unlawful financial arrangements;
11. examples of violations of the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b(b) and the Stark Law, 42 U.S.C. § 1395nn; and
12. a review of Ginsburg's contracting Policies and Procedures related to "Arrangements," as defined in Section III.F below, as developed pursuant to Section III.C and the personal obligations of each individual involved in the development or maintenance of Arrangements to know applicable legal requirements and Ginsburg's Policies and Procedures.

Each Covered Person shall annually certify, in writing or in electronic format if the training is computerized, that he or she has received the required training. The certification shall specify the date the training was received. The Compliance Contact shall retain the certifications, along

with all training materials. Ginsburg shall annually review the training, and, where appropriate, update the training to reflect changes in Federal health care program requirements, any issues discovered during the Legal IRO Review, and any other relevant information.

Ginsburg may provide the training required under this Agreement through appropriate computer-based training approaches. If Ginsburg chooses to provide computer-based training, he shall make available appropriately qualified and knowledgeable staff or trainers to answer questions or provide additional information to the individuals receiving such training.

The training materials shall be provided in the Implementation Report, and to the extent the training is revised, shall also be included in the Annual Reports. The certifications shall be made available to OIG, upon request.

**E. Third Party Billing**

1. Current Contract with Third Party Biller. If Ginsburg presently contracts with a third party billing company to submit claims to the Federal health care programs, Leonard Ginsburg represents that neither he nor any Ginsburg entity has an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in the third party billing company. Leonard Ginsburg further certifies that neither he nor any Ginsburg entity is employed by, nor do they act as a consultant to, the third party billing company. If Ginsburg intends to obtain an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or become employed by, or become a consultant to, any third party billing company during the term of this Agreement, Ginsburg shall notify OIG 30 days prior to any such proposed involvement.

Within 90 days after the Effective Date, Ginsburg shall obtain (and provide to OIG in the Implementation Report) a certification from the third party billing company that the company: (i) is presently in compliance with all Federal health care program requirements as they relate to the submission of claims to Federal health care programs; (ii) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; (iii) provides the required training in accordance with Section III.D of the Agreement for those employees involved in the preparation and submission of claims to Federal health care programs.

If Ginsburg contracts with a new third party billing company during the term of this Agreement, Ginsburg shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this Section III.E.1.

2. Future Contract with Third Party Biller. If, at any time during the term of this Agreement, Ginsburg contracts with a third party billing company to submit claims to the Federal health care programs, at least 30 days prior to executing the contract, Leonard Ginsburg shall submit a certification indicating whether he or any Ginsburg entity has an ownership or control interest (as defined in 42 U.S.C. § 1320a – 3(a)(3)) in the third party billing company and whether he or any Ginsburg entity is employed by or acts as a consultant to the third party billing company.

Within 30 days after Ginsburg contracts with the third party billing company, Ginsburg shall obtain a certification from the third party billing company that the company: (i) is presently in compliance with all Federal health care program requirements as they relate to the submission of claims to Federal health care programs; (ii) has a policy of not employing any person who is excluded, debarred, suspended or otherwise ineligible to participate in Medicare or other Federal health care programs to perform any duties related directly or indirectly to the preparation or submission of claims to Federal health care programs; and (iii) provides the required training in accordance with Section III.D of the Agreement for those employees involved in the preparation and submission of claims to Federal health care programs.

If Ginsburg contracts with a new third party billing company during the term of this Agreement, Ginsburg shall, within 30 days of entering into such contract, obtain and send to OIG the certification described in this Section III.E.1.

**F. Contractual Compliance of Contractual Arrangements with the Anti-Kickback Statute and the Stark Law**



Within 90 days after the Effective Date, Ginsburg shall establish policies and procedures regarding his actual or potential relationships with sources of referrals of health care business to or from Ginsburg (Arrangements). These policies and procedures shall be reasonably designed to ensure that each contractor relationship does not violate the Anti-Kickback Statute and/or the Stark Law. For the purposes of this section, “source” shall mean any physician, contractor, vendor, or agent, and the term “health care business or referrals” shall be read to include referring, recommending, arranging for, ordering, leasing, or purchasing any good, facility, item, or service for which payment may be made in whole or in part by a Federal health care program. The party(ies) to an Arrangement other than Ginsburg are referred herein as a “contractor.”

Before entering into new Arrangements or renewing existing Arrangements, Ginsburg shall ensure that all such Arrangements are in compliance with the Anti-Kickback Statute and Stark Law, and the regulations, directives, and guidance related to these statutes, and comply with the following requirements:

1. Ginsburg’s agreement with the contractor shall be set forth in writing and signed by Ginsburg and the contractor(s);
2. The agreement shall include a provision that the contractor shall comply with Ginsburg’s compliance program. Additionally, Ginsburg shall provide each contractor with a copy of Ginsburg’s Stark and Anti-Kickback Policies and Procedures;
3. Leonard Ginsburg shall certify and shall require the contractor(s) to certify, at the time of signing the agreement with the contractor and upon renewal of such agreement, that the contractor relationship is not intended to generate referrals for services or supplies for which payment may be made in whole or in part under any Federal health care program; and
4. Ginsburg shall require the contractor(s) to certify at the time of signing the written agreement that the contractor(s) shall comply with Ginsburg’s compliance program and with the Anti-Kickback Statute and the Stark Law.

Ginsburg shall retain, and make available to OIG upon request, copies of all written agreements with contractors subject to this Section and, to the extent available, all non-privileged communications related to the

contractor relationships and the actual performance of the duties under the contractor relationships.

**G. Review Procedures**

**1. General Description.**

a. *Engagement of Legal Independent Review Organization.* Within 90 days after the Effective Date, Ginsburg shall retain competent outside legal counsel with experience in the Anti-Kickback Statute and Stark Law to serve as the Legal Independent Review Organization (“Legal IRO”) in accordance with the specification in Appendix A. The Legal IRO shall assess, along with Ginsburg, whether it can perform the applicable review engagement in a professionally independent fashion taking into account any other business relationships or engagements that may exist.

b. *Type and Frequency of Review.* The Legal IRO shall conduct a legal review of the current Arrangements as detailed in Appendix A to determine whether they violate the Anti-Kickback Statute and Stark Law (Arrangements Review). The Arrangements Review shall be performed annually and shall cover each of the Reporting Periods. The Legal IRO shall perform (or oversee the performance by equally independent third parties engaged by the Legal IRO) all components of each Arrangements Review.

c. *Retention of Records.* The Legal IRO and Ginsburg shall retain and make available to OIG, upon request, (1) copies of all Arrangements; (2) all documents relating to the Arrangements, including approval forms, review notes, fair market value determinations, time sheets, service logs, and payment documentation (e.g., Form 1099s and records of checks or wire transfers); and (3) all nonprivileged communications, including work papers, supporting documentation, correspondence, interview reports, and draft reports related to the Arrangements and the performance of duties under the Arrangements.

d. *Independence/Objectivity Certification.* The Legal IRO shall include in its report(s) to Ginsburg a certification or sworn affidavit that it has evaluated its professional independence and/or objectivity, as appropriate to the nature of the engagement, and that it has concluded that it is, in fact, independent and/or objective.

2. Arrangements Review. The Legal IRO shall conduct a review of the Arrangements. The purpose of the review will be to identify Ginsburg's current Arrangements that could pose a risk of violating the Anti-Kickback Statute and/or the Stark Law and to recommend appropriate corrective actions when those risks have been identified. The Legal IRO and Ginsburg shall follow the specifications for the Arrangements Review detailed in Appendix A, which is incorporated by reference into this Agreement. Nothing in this Section III affects Ginsburg's responsibilities of, or liabilities under, any criminal, civil, or administrative laws or regulations applicable to any Federal health care program including, but not limited to, the Anti-Kickback Statute and/or the Stark Law.
3. Summary Report for the Arrangements Review. As further specified in Appendix A, the Legal IRO shall prepare reports for each Reporting Period within 60 days of the end of each Reporting Period summarizing the findings regarding the Arrangements Review, including a summary of how many Arrangements were reviewed and how many Outlier Arrangements (as defined in Appendix A) were identified and a certification from the Legal IRO that the Arrangements Review has been conducted reasonably and in good faith.

## **H. Ineligible Persons**

1. Definitions. For purposes of this Agreement:
  - a. An "Ineligible Person" shall include an individual or entity who:
    - (i) is currently excluded, debarred, suspended, or otherwise ineligible to participate in the Federal health care programs or in Federal procurement or nonprocurement programs; or
    - (ii) has been convicted of a criminal offense that falls within the ambit of 42 U.S.C. § 1320a-7(a), but has not yet been excluded, debarred, suspended, or otherwise declared ineligible.
  - b. "Exclusion Lists" include: (i) the HHS/OIG List of Excluded Individuals/Entities (available through the Internet at <http://oig.hhs.gov>); and (ii) the General Services Administration's List of Parties Excluded from Federal Programs (available through the Internet at <http://www.epls.arnet.gov>)
2. Screening Requirements. Ginsburg shall ensure that all prospective and current owners, officers, directors, associates, employees,

contractors, and agents of Ginsburg are not Ineligible Persons. To ensure that such individuals and entities are not Ineligible Persons, Ginsburg shall require such individuals and entities to disclose immediately any debarment, exclusion, suspension, or other event that makes such person an Ineligible Person. Prior to engaging the services of such individuals and entities, Ginsburg shall screen such individuals and entities against the Exclusion Lists. In addition, Ginsburg shall:

- a. Within 90 days after the Effective Date, review his list of the individuals and entities identified in Section III.H.2 against the Exclusion Lists; and
- b. Review its list of individuals and entities identified in Section III.H.2 against the Exclusion Lists annually.

Nothing in this Section affects the responsibility of (or liability for) Ginsburg to refrain from billing Federal health care programs for services of the Ineligible Person.

3. Removal Requirement. If Ginsburg has notice that any individuals or entities in one of the positions identified in Section III.H.2 has become an Ineligible Person, Ginsburg shall remove such individual or entity from responsibility for, or involvement with, Ginsburg's business operations related to the Federal health care programs and shall remove such individual or entity from any position for which the individual's or entity's compensation or the items or services rendered, ordered, or prescribed by the person are paid in whole or part, directly or indirectly, by Federal health care programs or otherwise with Federal funds at least until such time as the individual or entity is reinstated into participation in the Federal health care programs.
4. Pending Charges and Proposed Exclusions. If Ginsburg has notice that an individual or entity identified in Section III.H.2 is charged with a criminal offense that falls within the ambit of 42 U.S.C. §1320a-7(a) or is proposed for exclusion during his, her, or its employment, involvement or contract term, Ginsburg shall take all appropriate actions to ensure that the responsibilities of that individual or entity have not and shall not adversely affect the quality of care rendered to any beneficiary, patient, or resident, or the accuracy of any claims submitted to any Federal health care program.

**I. Notification of Government Investigation or Legal Proceedings**

Within 30 days after discovery, Ginsburg shall notify OIG, in writing, of any ongoing investigation or legal proceeding known to Ginsburg conducted or brought by a governmental entity or its agents involving an allegation that Ginsburg has committed a crime or has engaged in fraudulent activities. This notification shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding. Ginsburg shall also provide written notice to OIG within 30 days after the resolution of the matter, and shall provide OIG with a description of the findings and/or results of the proceedings, if any.

**J. Reporting**

**1. Overpayments**

a. *Definition of Overpayments.* For purposes of this Agreement, an “Overpayment” shall mean the amount of money Ginsburg has received in excess of the amount due and payable under any Federal health care program requirements.

b. *Reporting of Overpayments.* If, at any time, Ginsburg identifies or learns of any Overpayment, Ginsburg shall notify the payor (e.g., Medicare fiscal intermediary or carrier) within 30 days after identification of the Overpayment and take remedial steps within 60 days after identification (or such additional time as may be agreed to by the payor) to correct the problem, including preventing the underlying problem and the Overpayment from recurring. Also, within 30 days after identification of the Overpayment, Ginsburg shall repay the Overpayment to the appropriate payor to the extent such Overpayment has been quantified. If not yet quantified within 30 days after identification, Ginsburg shall notify the payor at that time of its efforts to quantify the Overpayment amount along with a schedule of when such work is expected to be completed. Notification and repayment to the payor shall be done in accordance with the payor’s policies, and for Medicare contractors shall include the information contained on the Overpayment Refund Form, provided as Attachment 1 to Appendix B to this Agreement. Notwithstanding the above, notification and repayment of any Overpayment amount that

routinely is reconciled or adjusted pursuant to policies and procedures established by the payor should be handled in accordance with such policies and procedures.

2. Reportable Events.

a. *Definition of Reportable Event.* For purposes of this Agreement, a “Reportable Event” means anything that involves:

- i. a substantial Overpayment; or
- ii. a matter that a reasonable person would consider a probable violation of criminal, civil, or administrative laws applicable to any Federal health care program for which penalties or exclusion may be authorized.

A Reportable Event may be the result of an isolated event or a series of occurrences.

b. *Reporting of Reportable Event.* If Ginsburg determines (after a reasonable opportunity to conduct an appropriate review or investigation of the allegations) through any means that there is a Reportable Event, Ginsburg shall notify OIG, in writing, within 30 days after making the determination that the Reportable Event exists. The report to OIG shall include the following information:

i. If the Reportable Event results in an Overpayment, the report to OIG shall be made at the same time as the notification to the payor required in Section III.I.1, and shall include all of the information on the Overpayment Refund Form, as well as:

(A) the payor’s name, address, and contact person to whom the Overpayment was sent; and

(B) the date of the check and identification number (or electronic transaction number) by which the Overpayment was repaid/refunded;

ii. a complete description of the Reportable Event, including the relevant facts, persons involved, and legal and Federal health care program authorities implicated;

- iii. a description of Ginsburg's actions taken to correct the Reportable Event; and
- iv. any further steps Ginsburg plans to take to address the Reportable Event and prevent it from recurring.

#### **IV. NEW BUSINESS UNITS AND LOCATIONS**

In the event that, after the Effective Date, Ginsburg changes locations or sells, closes, purchases, or establishes a new business unit or location related to the furnishing of items or services that may be reimbursed by Federal health care programs, Ginsburg shall notify OIG of this fact as soon as possible, but no later than 30 days after the date of change of location, sale, closure, purchase, or establishment. This notification shall include the address of the new business unit or location, phone number, fax number, Medicare Provider number, provider identification number, and/or supplier number, and the corresponding contractor's name and address that issued each number. Each new business unit or location and all Covered Persons at each new business unit or location shall be subject to the applicable requirements in this Agreement.

Before Ginsburg becomes an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Ginsburg shall notify that party of this Agreement. This notification shall include a copy of the Agreement, a statement indicating the remaining term of the Agreement, and a summary of Ginsburg's obligations under the Agreement. In addition, Ginsburg shall notify OIG of such relationship in his next Annual Report.

#### **V. REPORTS**

##### **A. Implementation Report**

Within 120 days after the Effective Date, Ginsburg shall submit a written report to OIG summarizing the status of its implementation of the requirements of this Agreement (Implementation Report). The Implementation Report shall, at a minimum, include:

1. the Compliance Contact's name, address, and phone number, a description of any other job responsibilities performed by the Compliance Contact, and the date the Compliance Contact was appointed;

2. a copy of the notice Ginsburg posted in his office as required by Section III.B, a description of where the notice is posted, and the date the notice was posted;
3. a copy of the written Policies and Procedures required by Section III.C of this Agreement and the date these Policies and Procedures were implemented and distributed;
4. a copy of all training materials used for the training session(s) required by Section III.D, a description of the training, including a summary of the topics covered, the length of each session, and a schedule of when the training session(s) were held;
5. a copy of the certification from the third party billing company required by Section III.E of the Agreement;
6. the name and qualifications of the Legal IRO, a summary/description of all engagements between Ginsburg and the Legal IRO, including the proposed start and completion dates of the first annual Arrangements Review;
7. a copy of the Legal IRO's engagement letter, including the length of the engagement;
8. a certification from the Legal IRO regarding its professional independence and/or objectivity with respect to Ginsburg;
9. a description of Ginsburg's process to screen Covered Persons to determine if they are ineligible;
10. a summary of personnel actions (other than hiring) taken pursuant to Section III.H, the name, title and responsibilities of any person who is determined to be an Ineligible Person under Section III.H, and the actions taken in response to the obligations set forth in Section III.H;
11. a list of all Ginsburg's locations (including locations and mailing addresses), the corresponding name under which each location is doing business, the corresponding phone numbers and fax numbers, each location's Medicare Provider number(s), provider identification number(s), and/or supplier number(s), and the name and address of each contractor to which Ginsburg currently submits claims;



12. if Ginsburg became an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Ginsburg shall inform OIG of the name, location, relationship, and his responsibilities with respect Ginsburg's employment or contract;

13. a certification by the Compliance Contact that:

a. the written Policies and Procedures required by Section III.C of this Agreement have been developed, are being implemented, and have been distributed to all Covered Persons; and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C of this Agreement;

b. all Covered Persons have completed the applicable training required by Section III.D of this Agreement; and that all Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D of this Agreement;

c. all owners, officers, directors, associates, employees, contractors, and agents that were hired or engaged since the execution of the Agreement were screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Ginsburg, as required by Section III.H of this Agreement; and

d. all current owners, officers, directors, associates, employees, contractors, and agents of Ginsburg were screened against the Exclusion Lists within 90 days after the Effective Date of this Agreement, as required by Section III.H of this Agreement and the date(s) of the screening.

14. a certification signed by Leonard Ginsburg certifying (a) to the best of his knowledge, except as otherwise described in the Implementation Report, Ginsburg is in compliance with all of the requirements of this Agreement and (b) Ginsburg has reviewed the Implementation Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

**B. Annual Reports**

Ginsburg shall submit to OIG Annual Reports with respect to the status of, and findings regarding, Ginsburg's compliance activities for each of the three Reporting Periods (Annual Report).

Each Annual Report shall, at a minimum, include:

1. any change in the name, address, phone number, or job responsibilities of Ginsburg's Compliance Contact;
2. any changes to the posted notice and the reason for such changes;
3. a copy of any new compliance-related Policies and Procedures;
4. a summary of any changes or amendments to the written Policies and Procedures required by Section III.C and the reason(s) for such changes (e.g., change in contractor policies);
5. a copy of all training materials used for the training session(s) required by Section III.D (to the extent they have not already been provided as part of the Implementation Report); a description of the training, including a summary of the topics covered; the length of each session; and a schedule of when the training session(s) was held;
6. a copy of the certification from the third party billing company required by Section III.E of the Agreement, if applicable;
7. a complete copy of the Summary report prepared pursuant to the Arrangements Review for the relevant Reporting Period, required by Section III.G;
8. if applicable, a certification by Leonard Ginsburg stating that Ginsburg does not currently and has not submitted any cost reports to any Federal health care programs since this Agreement was executed;
9. Ginsburg's response and corrective action plan(s) related to any issues raised or recommendations made by the Legal IRO, as a result of the Arrangements Review performed pursuant to Section III.G;
10. a summary/description of all engagements between Ginsburg and the Legal IRO, if different from what was submitted as part of the Implementation Report;

11. a certification from the Legal IRO regarding its professional independence and/or objectivity to Ginsburg;
12. a description of Ginsburg's process to screen Covered Persons to determine if they are ineligible (to the extent it has changed from the Implementation Report);
13. a summary of personnel actions/other than hiring taken pursuant to Section III.H; the name, titles and responsibilities of any person who is determined to be an Ineligible Person under Section III.H; and Ginsburg's actions taken in response to the obligations set forth in Section III.H;
14. a summary describing any ongoing investigation or legal proceeding required to have been reported pursuant to Section III.I. The summary shall include a description of the allegation, the identity of the investigating or prosecuting agency, and the status of such investigation or legal proceeding;
15. a summary of Reportable Events (as defined in Section III.J) identified during the Reporting Period and the status of any corrective and preventative action relating to all such Reportable Events;
16. a report of the aggregate Overpayments that have been returned to the Federal health care programs. Overpayment amounts shall be broken down into the following categories: Medicare, Medicaid, and other Federal health care programs;
17. a description of all changes to the most recently provided list of Ginsburg's locations (including addresses) as required by Section IV. Include the corresponding phone numbers, fax numbers, each location's Medicare Provider Number(s), provider identification number(s), and/or supplier number(s), and the name and address of the contractor that issued each number;
18. if Ginsburg became an employee or contractor with another party related to the furnishing of items or services that may be reimbursed by Federal health care programs, Ginsburg shall inform OIG of the name, location, relationship, and his responsibilities with respect to Ginsburg's employment or contract;
19. A certification, where appropriate, by the Compliance Contact that certifies that:

a. the written Policies and Procedures have been reviewed during the Reporting Period, as required by Section III.B of this Agreement, and that all Covered Persons have executed the written Policies and Procedures certification in accordance with the timeframe required by Section III.C of this Agreement;

b. all Covered Persons have completed the applicable training required by Section III.D of this Agreement and that all Covered Persons have executed the applicable training certification(s) in accordance with the timeframe required by Section III.D of this Agreement;

c. all owners, officers, directors, associates, employees, contractors, and agents that were hired, engaged or otherwise involved with Ginsburg during the Reporting Period have been screened against the Exclusion Lists and asked to disclose if they are excluded, debarred, suspended, or are otherwise considered an Ineligible Person, prior to entering into their relationship with Ginsburg, as required by Section III.H of this Agreement; and

d. all owners, officers, directors, associates, employees, contractors, and agents (employed, engaged or otherwise involved with Ginsburg for the entire Reporting Period) were screened against the Exclusion Lists during the Reporting Period, in accordance with Section III.H of this Agreement and the date(s) they were screened;

20. a certification signed by Leonard Ginsburg certifying that (a) to the best of his knowledge, except as otherwise described in the applicable Report, Ginsburg is in compliance with all of the requirements of this Agreement and (b) Ginsburg has reviewed the Annual Report and has made a reasonable inquiry regarding its content and believes that the information is accurate and truthful.

The first Annual Report shall be received by OIG no later than 60 days after the end of the first Reporting Period. Subsequent Annual Reports shall be received by OIG no later than the anniversary date of the due date of the first Annual Report.

**C. Designation of Information**

Ginsburg shall clearly identify any portions of its submissions that he believes are trade secrets, or information that is commercial or financial and privileged or confidential, and therefore potentially exempt from disclosure

under the Freedom of Information Act (FOIA), 5 U.S.C. § 552. Ginsburg shall refrain from identifying any information as exempt from disclosure if that information does not meet the criteria for exemption from disclosure under FOIA.

## **VI. NOTIFICATIONS AND SUBMISSION OF REPORTS**

Unless otherwise stated in writing after the Effective Date, all notifications and Reports required under this Agreement shall be submitted to the following entities:

OIG:           Administrative and Civil Remedies Branch  
                  Office of Counsel to the Inspector General  
                  Office of Inspector General  
                  U.S. Department of Health and Human Services  
                  Cohen Building, Room 5527  
                  330 Independence Avenue, SW  
                  Washington, DC 20201  
                  Telephone: (202) 619-2078  
                  Facsimile: (202) 205-0604

Ginsburg:     Ernest L. Tsoules, Esq.  
                  Tsoules, Sweeney Dubrow, Kepner & Martin, LLC  
                  707 Eagleview Blvd., Suite 100  
                  Exton, PA 19341  
                  Telephone: (610) 458-0600  
                  Facsimile: (610) 458-0602

Unless otherwise specified, all notifications and Reports required by this Agreement shall be made by certified mail, overnight mail, hand delivery, or other means, provided that there is proof that such notification was received. For purposes of this requirement, internal facsimile confirmation sheets do not constitute proof of receipt.

## **VII. OIG INSPECTION, AUDIT AND REVIEW RIGHTS**

In addition to any other rights OIG may have by statute, regulation, or contract, OIG or its duly authorized representative(s) may examine or request copies of Ginsburg's books, records, and other documents and supporting materials and/or conduct on-site reviews of any of Ginsburg's locations for the purpose of verifying and evaluating: (a) Ginsburg's compliance with the terms of this CIA; and (b) Ginsburg's compliance with the requirements of the Federal health care programs in which he participates. The documentation described above shall be made available by Ginsburg to OIG or its duly authorized representative(s) at all

reasonable times for inspection, audit, or reproduction. The OIG shall make reasonable efforts to perform such reviews without disruption of patient care and in a confidential manner. Furthermore, for purposes of this provision, OIG or its duly authorized representative(s) may interview any of Ginsburg's employees, contractors, or agents who consent to be interviewed at the individual's place of business during normal business hours or at such other place and time as may be mutually agreed upon between the individual and OIG. Ginsburg shall assist OIG or its duly authorized representative(s) in contacting and arranging interviews with such individuals upon OIG's request. Ginsburg's employees may elect to be interviewed with or without a representative of Ginsburg present.

#### **VIII. DOCUMENT AND RECORD RETENTION**

Ginsburg shall maintain for inspection all documents and records relating to reimbursement from the Federal health care programs, or to compliance with this Agreement, for six years (or longer if otherwise required by law).

#### **IX. DISCLOSURES**

Consistent with HHS's FOIA procedures, set forth in 45 C.F.R. Part 5, OIG shall make a reasonable effort to notify Ginsburg prior to any release by OIG of information submitted by Ginsburg pursuant to its obligations under this Agreement and identified upon submission by Ginsburg as trade secrets, or information that is commercial or financial and privileged or confidential, under the FOIA rules. With respect to such releases, Ginsburg shall have the rights set forth at 45 C.F.R. § 5.65(d). Nothing in this Agreement, or any communication or report made pursuant to this Agreement, shall constitute or be construed as a waiver by Ginsburg of his attorney-client, work product, peer review, or other applicable privileges. Notwithstanding that fact, the existence of any such privilege does not affect Ginsburg's obligation to comply with the provisions of this Agreement.

#### **X. BREACH AND DEFAULT PROVISIONS**

Ginsburg is expected to fully and timely comply with all of its Agreement obligations.

##### **A. Stipulated Penalties for Failure to Comply with Certain Obligations**

As a contractual remedy, Ginsburg and OIG hereby agree that failure to comply with certain obligations set forth in this Agreement may lead to the imposition of the following monetary penalties (hereinafter referred to as "Stipulated Penalties") in accordance with the following provisions.

1. A Stipulated Penalty of \$750 (which shall begin to accrue on the date after the date the obligation has become due) for each day Ginsburg fails to:

- a. have in place a Compliance Contact as required in Section III.A;
- b. establish and/or post the notice that meets the requirements of Section III.B;
- c. implement and make available the Policies and Procedures required in Section III.C;
- d. establish a training program that meets the requirements of Section III.D of the Agreement and provide the applicable training to Covered Persons (unless a reasonable request for an extension of time has previously been submitted to and approved by OIG pursuant to Section X.B of this CIA) within the timeframe required by Section III.D;
- e. retain a Legal IRO within the timeframe required in Section III.G.1, or to submit the Legal IRO's annual Arrangements Review Summary Report as required in Section III.G and Appendix A;
- f. meet any of the deadlines for the submission of the Implementation Report or the Annual Reports to OIG;
- g. obtain a certification from the third party biller, send the third party biller certification to OIG in accordance with the requirements of Section III.E, or notify OIG within 30 days prior to Ginsburg obtaining an ownership or control interest (as defined in 42 U.S.C. § 1320a-3(a)(3)) in, or becoming employed by, or becoming a consultant to, any third party billing company;
- h. obtain and/or maintain the following documentation: Policies and Procedures certifications in accordance with the requirements of Section III.C, training certification(s) in accordance with the requirements of Section III.D, and/or documentation of screening and disclosure requirements in accordance with the requirements of Section III.H.2;
- i. screen current or prospective owners, officers, directors, associates, employees, contractors or agents in accordance with the requirements of Section III.H; or require owners, officers, directors,

associates, employees, contractors or agents to disclose if they are debarred, excluded, suspended or are otherwise considered an Ineligible Person in accordance with the requirements of Section III.H; or

j. notify OIG of a Government investigation or legal proceeding, in accordance with the requirements of Section III.I.

2. A Stipulated Penalty of \$750 for each day Ginsburg fails to grant access to the information or documentation as required in Section VII of this Agreement. (This Stipulated Penalty shall begin to accrue on the date Ginsburg fails to grant access.)

3. A Stipulated Penalty of \$5,000 for each false certification submitted by or on behalf of Ginsburg as part of its Implementation Report, Annual Report, additional documentation to a Report (as requested by OIG), or otherwise required by this Agreement.

4. A Stipulated Penalty of \$750 for each day Ginsburg fails to comply fully and adequately with any obligation of this Agreement. In its notice to Ginsburg, the OIG shall state the specific grounds for its determination that Ginsburg has failed to comply fully and adequately with the Agreement obligation(s) at issue and steps the Ginsburg shall take to comply with the Agreement. (This Stipulated Penalty shall begin to accrue 10 days after the date Ginsburg receives this notice from the OIG of the failure to comply.) A Stipulated Penalty as described in this Subsection shall not be demanded for any violation for which the OIG has sought a Stipulated Penalty under Subsections 1-4 of this Section.

**B. Timely Written Requests for Extensions**

Ginsburg may, in advance of the due date, submit a timely written request for an extension of time to perform any act or file any notification or Report required by this Agreement. Notwithstanding any other provision in this Section, if OIG grants the timely written request with respect to an act, notification, or Report, Stipulated Penalties for failure to perform the act or file the notification or Report shall not begin to accrue until one day after Ginsburg fails to meet the revised deadline set by OIG. Notwithstanding any other provision in this Section, if OIG denies such a timely written request, Stipulated Penalties for failure to perform the act or file the notification or Report shall not begin to accrue until three business days after Ginsburg receives OIG's written denial of such request or the original due date, whichever is later. A "timely written request" is defined as a



request in writing received by OIG at least five business days prior to the date by which any act is due to be performed or any notification or report is due to be filed.

**C. Payment of Stipulated Penalties.**

1. Demand Letter. Upon a finding that Ginsburg has failed to comply with any of the obligations described in Section X.A and after determining that Stipulated Penalties are appropriate, OIG shall notify Ginsburg of: (a) Ginsburg's failure to comply; and (b) OIG's exercise of its contractual right to demand payment of the Stipulated Penalties (this notification is referred to as the "Demand Letter").

2. Response to Demand Letter. Within 10 days of the receipt of the Demand Letter, Ginsburg shall either: (a) cure the breach to OIG's satisfaction and pay the applicable Stipulated Penalties; or (b) send in writing to OIG a request for a hearing before an HHS administrative law judge ("ALJ") to dispute OIG's determination of noncompliance, pursuant to the agreed upon provisions set forth below in Section X.E. In the event Ginsburg elects to request an ALJ hearing, the Stipulated Penalties shall continue to accrue until Ginsburg cures, to OIG's satisfaction, the alleged breach in dispute. Failure to respond to the Demand Letter in one of these two manners within the allowed time period shall be considered a material breach of this Agreement and shall be grounds for exclusion under Section X.D.

3. Form of Payment. Payment of the Stipulated Penalties shall be made by certified or cashier's check, payable to: "Secretary of the Department of Health and Human Services," and submitted to OIG at the address set forth in Section VI.

4. Independence from Material Breach Determination. Except as set forth in Section X.D.1.c, these provisions for payment of Stipulated Penalties shall not affect or otherwise set a standard for OIG's decision that Ginsburg has materially breached this Agreement, which decision shall be made at OIG's discretion and shall be governed by the provisions in Section X.D, below.

**D. Exclusion for Material Breach of this Agreement**

1. Definition of Material Breach. A material breach of this Agreement means:

- a. a failure by Ginsburg to report a Reportable Event, take corrective action and make the appropriate refunds, as required in Section III.I;
- b. a repeated or flagrant violation of the obligations under this Agreement, including, but not limited to, the obligations addressed in Section X.A;
- c. a failure to respond to a Demand Letter concerning the payment of Stipulated Penalties in accordance with Section X.C; or
- d. a failure to engage and use a Legal IRO in accordance with Section III.F.

2. Notice of Material Breach and Intent to Exclude. The parties agree that a material breach of this Agreement by Ginsburg constitutes an independent basis for Ginsburg's exclusion from participation in the Federal health care programs. Upon a determination by OIG that Ginsburg has materially breached this Agreement and that exclusion is the appropriate remedy, OIG shall notify Ginsburg of: (a) Ginsburg's material breach; and (b) OIG's intent to exercise its contractual right to impose exclusion (this notification is hereinafter referred to as the "Notice of Material Breach and Intent to Exclude").

3. Opportunity to Cure. Ginsburg shall have 30 days from the date of receipt of the Notice of Material Breach and Intent to Exclude to demonstrate to OIG's satisfaction that:

- a. Ginsburg is in compliance with the obligations of the Agreement cited by OIG as being the basis for the material breach;
- b. the alleged material breach has been cured; or
- c. the alleged material breach cannot be cured within the 30-day period, but that: (i) Ginsburg has begun to take action to cure the material breach; (ii) Ginsburg is pursuing such action with due diligence; and (iii) Ginsburg has provided to OIG a reasonable timetable for curing the material breach.

4. Exclusion Letter. If at the conclusion of the 30-day period, Ginsburg fails to satisfy the requirements of Section X.D.3, OIG may exclude Ginsburg from participation in the Federal health care programs. OIG shall notify Ginsburg in writing of its determination to exclude Ginsburg (this

letter shall be referred to hereinafter as the “Exclusion Letter”). Subject to the Dispute Resolution provisions in Section X.E, below, the exclusion shall go into effect 30 days after the date of Ginsburg’s receipt of the Exclusion Letter. The exclusion shall have national effect and shall also apply to all other Federal procurement and non-procurement programs. Reinstatement to program participation is not automatic. After the end of the period of exclusion, Ginsburg may apply for reinstatement, by submitting a written request for reinstatement in accordance with the provisions at 42 C.F.R. §§ 1001.3001-.3004.

**E. Dispute Resolution**

1. Review Rights. Upon OIG’s delivery to Ginsburg of its Demand Letter or of its Exclusion Letter, and as an agreed-upon contractual remedy for the resolution of disputes arising under this Agreement, Ginsburg shall be afforded certain review rights comparable to the ones that are provided in 42 U.S.C. § 1320a-7(f) and 42 C.F.R. Part 1005 as if they applied to the Stipulated Penalties or exclusion sought pursuant to this Agreement. Specifically, OIG’s determination to demand payment of Stipulated Penalties or to seek exclusion shall be subject to review by an HHS ALJ and, in the event of an appeal, the HHS Departmental Appeals Board (“DAB”), in a manner consistent with the provisions in 42 C.F.R. § 1005.2-1005.21. Notwithstanding the language in 42 C.F.R. § 1005.2(c), the request for a hearing involving Stipulated Penalties shall be made within 10 days after the receipt of the Demand Letter and the request for a hearing involving exclusion shall be made within 25 days after receipt of the Exclusion Letter.

2. Stipulated Penalties Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for Stipulated Penalties under this Agreement shall be: (a) whether Ginsburg was in full and timely compliance with the obligations of this Agreement for which OIG demands payment; and (b) the period of noncompliance. Ginsburg shall have the burden of proving its full and timely compliance and the steps taken to cure the noncompliance, if any. OIG shall not have the right to appeal to the DAB an adverse ALJ decision related to Stipulated Penalties. If the ALJ agrees with OIG with regard to a finding of a breach of this Agreement and orders Ginsburg to pay Stipulated Penalties, such Stipulated Penalties shall become due and payable 20 days after the ALJ issues such a decision unless Ginsburg requests review of the ALJ decision by the DAB. If the ALJ decision is properly appealed to the DAB and the DAB upholds the

determination of OIG, the Stipulated Penalties shall become due and payable 20 days after the DAB issues its decision.

3. Exclusion Review. Notwithstanding any provision of Title 42 of the United States Code or Chapter 42 of the Code of Federal Regulations, the only issues in a proceeding for exclusion based on a material breach of this Agreement shall be:

- a. whether Ginsburg was in material breach of this Agreement;
- b. whether such breach was continuing on the date of the Exclusion Letter; and
- c. whether the alleged material breach could not have been cured within the 30 day period, but that: i. Ginsburg had begun to take action to cure the material breach within that period; ii. Ginsburg has pursued and is pursuing such action with due diligence; and iii. Ginsburg provided to OIG within that period a reasonable timetable for curing the material breach and Ginsburg has followed the timetable.

For purposes of the exclusion herein, exclusion shall take effect only after an ALJ decision favorable to OIG, or, if the ALJ rules for Ginsburg, only after a DAB decision in favor of OIG. Ginsburg's election of its contractual right to appeal to the DAB shall not abrogate OIG's authority to exclude Ginsburg upon the issuance of an ALJ's decision in favor of OIG. If the ALJ sustains the determination of OIG and determines that exclusion is authorized, such exclusion shall take effect 20 days after the ALJ issues such a decision, notwithstanding that Ginsburg may request review of the ALJ decision by the DAB. If the DAB finds in favor of OIG after an ALJ decision adverse to OIG, the exclusion shall take effect 20 days after the DAB decision. Ginsburg shall waive the right to any notice of such an exclusion if a decision upholding the exclusion is rendered by the ALJ or DAB. If the DAB finds in favor of Ginsburg, he shall be reinstated effective on the date of the original exclusion.

4. Finality of Decision. The review by an ALJ or DAB provided for above shall not be considered to be an appeal right arising under any statutes or regulations. Consequently, the parties to this Agreement agree that the DAB's decision (or the ALJ's decision if not appealed) shall be considered final for all purposes under this Agreement.

## **XI. EFFECTIVE AND BINDING AGREEMENT**

Consistent with the provisions in the Settlement Agreement pursuant to which this Agreement is entered, and into which this Agreement is incorporated, Ginsburg and OIG agree as follows:

- A. This Agreement shall be binding on the successors, assigns, and transferees of Ginsburg;
- B. This Agreement shall become final and binding on the date the final signature is obtained on the Agreement;
- C. Any modifications to this Agreement shall be made with the prior written consent of the parties to this Agreement;
- D. OIG may agree to a suspension of Ginsburg's obligations under this Agreement in the event of Ginsburg's cessation of participation in Federal health care programs. If Ginsburg withdraws from participation in Federal health care programs and is relieved of his Agreement obligations by OIG, Ginsburg shall notify OIG 30 days in advance of Ginsburg's intent to reapply as a participating provider or supplier with any Federal health care program. Upon receipt of such notification, OIG shall evaluate whether the Agreement shall be reactivated or modified;
- E. All requirements and remedies set forth in this Agreement are in addition to, and do not effect, (1) Ginsburg's responsibility to follow all applicable Federal health care program requirements or (2) the Government's right to impose appropriate remedies for failure to follow applicable program requirements; and
- F. The undersigned Ginsburg signatories represent and warrant that they are authorized to execute this Agreement. The undersigned OIG signatory represents that he is signing this Agreement in his official capacity and that he is authorized to execute this Agreement.

IN WITNESS WHEREOF, the parties hereto affix their signatures:

**LEONARD GINSBURG, M.D.**

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Leonard Ginsburg, M.D.

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Date

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Eric Sitarchuk, Esq.  
Counsel for Ginsburg

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Date

**OFFICE OF INSPECTOR GENERAL OF  
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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Larry J. Goldberg  
Assistant Inspector General for Legal Affairs  
Office of Counsel to the Inspector General  
Office of Inspector General  
U. S. Department of Health and Human Services

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Date